Remarks

Claims 1 to 4, 6 to 17, 19, 20, 22 to 25, 27, and 28 are pending in the application. All claims have been rejected.

Claims 11 to 17, 19, 20, 22 to 25, 27, and 28 were rejected under 35 U.S.C. §112, first paragraph, because the examiner contended that the specification does not enable a person skilled in the art to practice the claimed inventions. The examiner asserts that there is no support for a limitation of a dielectric constant greater than 25, "unless the mix is 1% fatty acid C8/C10 at pH less than 4.0...." Action, p. 2. The examiner then listed the relevant factors in determining whether there is adequate support under 35 U.S.C. §112, first paragraph. Applicants appreciate the examiner's recitation of these factors, and the detailed analysis of each.

Initially, it is noted that the term "polar" has been deleted from these claims because it may be a source of confusion for the examiner when dielectric constants are being specified by number as opposed to a more general term such as "polar." Indeed, to those of ordinary skill in the art, the numerical value of a dielectric constant can be interchangeable with the relative terms "polar" or "non-polar," so the use of both could be considered redundant. The claims rejected under 35 U.S.C. §112 now recite that the composition has a solvent with a dielectric constant greater than 25, without reference to it being "polar."

Applicants also note that the dielectric constant (the ratio of electric displacement to electric field intensity) is the most commonly used measure of the relative polarity or conductivity of a material. Brown W.H. 1995. Organic Chemistry (Harcourt Brace & Co., Orlando, FL). The range of dielectric constants can be generalized by the relative terms "polar" and "non-polar." The specific cut-off for such general terms can depend upon the technology and functions at issue. In this case, the general terms were used; examples were provided, such as

glycol, glycerol, ethylene glycol, and isopropanol; and specific ranges of dielectric constants were given, such as greater than 25, to differentiate the effective solvents for this invention. (Spec., p. 23, paras. 58 and 59.) Given these three different ways of explaining the same principle, it is Applicants' respectful contention, that one of ordinary skill in the art would have ample teachings for practicing the claimed inventions without undue experimentation.

As a brief summary for the purposes of the solvent in the invention, it is noted that the solubility of a solute in a solvent is dependent on the relative polarities of each i.e.: a polar solvent (high dielectric constant) will dissolve a polar solute and a non-polar solvent (low dielectric constant) will dissolve a non-polar solute. As it pertains to carboxylic acids in general, and the caprylic and capric acids utilized in this invention in particular, the shorter the carbon chain or non-polar (hydrophobic) component of the molecule relative to the polar (lipophobic) end of the molecule containing the carboxyl group (COOH), the greater the overall polarity of the molecule.

In examples in the current invention, the solutes (caprylic acid and capric acid, for example) which have carbon numbers of 8 and 10, respectively, are themselves non-polar (dielectric constant of 3.2 and below 4, respectively). Not surprisingly, they are very poorly soluble in water, which is itself very polar with a dielectric constant of 88. However, what is surprising is that these carboxylic acids are quite soluble in propylene glycol, glycerol and isopropanol which are also polar, although not quite as much as water, with dielectric constants of 32, 46 and 18.3, respectively. (Spec., p. 6, para. 20, for example.) These solvents have a lower polarity than water, but are still somewhat polar. Shrewsbury, RP, Laboratory Exercise 9. Pharmaceutics Laboratory, School of Pharmacy, University of North Carolina at Chapel Hill. 1996.

Further, in this case, the alteration of the polarity of the solute evidently shifts the fatty acids in question from their undissociated or molecular state to their dissociated or ionic state. This dissociated or polar conformation is the state of the molecule that can be germicidal. However, when the fatty acids are dissolved in such non polar solvents as mineral oil or corn oil, (dielectric constants of between 2 and 4) they remain undissociated and therefore, non germicidal. This phenomenon is illustrated when the germicidal efficacies of the caprylic/capric acids are compared in the various solvents tested with differing polarities (see tables listed in the application at pp. 25 and 26). This phenomenon was new and unexpected since there was no knowledge that caprylic and capric acids in question needed to be in their dissociated or polar state to be germicidal. This was also new and unexpected since it was not known that this polar, and therefore germicidal, state could be effectively achieved by dissolving the caprylic and capric acids directly into such a miscible solvent. All of these teachings were in the original application and enable one skilled in the art to practice the claimed invention regardless of whether the specific solvent is recited, the general term "polar" is used, or a range of dielectric constants is used.

Applicants stated in their April 10, 2007 amendment,

> The examiner also rejected claims 11, 17, and 24 which recited a lipophilic polar solvent having a dielectric constant greater than 25 as having "no support." Applicants respectfully disagree, and include herewith a Dielectric Constants Chart from ASI Instruments, Inc. that lists the dielectric constant for isopropyl alcohol as 18.3. Isopropanol was listed as a suitable lipophilic polar solvent at p.7, line 19 of the application. Therefore, dielectric constants as low as 18.3 are inherent in the listing of isopropanol and are supported by the original disclosure. Further, the specification at p. 23, lines 14 to 21 supports claims that distinguish between dielectric constants of 25 as relatively high and low. Therefore, the specification supports these claims and no amendment is believed to be necessary.

In addition, the specification at page 23, paragraph 60 states,

> It is believed that a greater degree of antimicrobial efficacy occurs when the fatty acids are solubilized in lipophilic high polarity solvents versus when they are solubilized in lipophilic low polarity solvents. When 1% by weight of a mixture of 55% C_8 and 40% C_{10} fatty acids is added to lipophilic, high polarity solvents such as propylene glycol, glycerol, ethylene glycol or isopropanol, the bactericidal efficacy against such organisms as Staphylococcus aureus and Escherichia coli is impressive.
>
> However, when the same concentration of fatty acids is solubilized in such low polarity lipophilic solvents such as corn oil or mineral oil, the bactericidal efficacy of the fatty acid component decreases significantly, with a large number of the organisms surviving the treatment.

Thus, Applicants respectfully submit that factors 3) and 4) listed at p. 2 in the Action relating to the skill in the art as being high, but that predictability is low, actually favor a finding that §112, first paragraph has been satisfied because one skilled in the art would have been taught the various types of solvents for use in the present invention, so long as, the dielectric constant of the solvent is high enough. *Specific examples* of suitable solvents with sufficiently high dielectric constants are given as glycol (35.6), glycerol (47), ethylene glycol (37), and isopropanol (18.3). The numbers in parentheses are not listed that way in the specification, but they are inherent values that are readily available on-line at asiinstr.com (copy attached hereto), and would have been known to one skilled in the art such as this, where it is high. Thus, there is nothing unpredictable about potential results of using alternate lipophilic solvents having a dielectric constant greater than 25, which was specifically taught by Applicants at p. 23, to be a suitable lower end solvent dielectric constants.

Claim 12 was also rejected under 35 U.S.C. §112, second paragraph because the examiner contends that ethylene is not a polar solvent. This claim has been amended to delete a comma, so that now the term is "ethylene glycol," which is a polar solvent within the scope of the present invention.

Claims 1 to 4, 6 to 12, 15 to 17, 19, 20, 22 to 25, and 28 were rejected under 35 U.S.C. §102(b) as being anticipated or, in the alternative, under 35 U.S.C. §103(a) as being obvious over *Kabara*. (Action, p. 3.)

Initially, Applicants respectfully note that the examiner has incorrectly stated the disclosure of *Kabara*. In one example, the examiner states, "The alcohol is 60% (page 6, lines 4-6) preferred, *but can be any suitable level.*" (Emphasis added.) Applicants submit that *Kabara* discloses a preferred embodiment "of about 5 to about 60%, more preferred at about 10 to about 30% and, in a highly preferred embodiment, at about 20 to about 25% and, in a highly preferred embodiment, at about 5 to about 10% by weight per volume of use..." (Page 6, top.) Thus, there is no disclosure of any alcohol concentration at "any suitable level." Indeed, the ranges and percentages by weight are taught in the preferred embodiments to be well below "about 60%." Applicants respectfully submit that this mistaken view of *Kabara*'s disclosure fundamentally undermines the rejections because *Kabara* did not recognize the synergy that resulted from the combination of greater than 60% propylene glycol being used with fatty acids as claimed in the present invention. As discussed in detail below, *Kabara* makes no mention of enhancing antimicrobial efficacy using a higher percentage by weight of a solvent, and therefore does not anticipate or render obvious the claimed invention.

More importantly, *Kabara* teaches a composition having as its primary ingredient a fatty acid ester. That ester is mixed with fatty acids, for example, but there is no composition disclosed in *Kabara* that has no fatty acid ester. It is Applicants' position that *Kabara* does not enable a composition that does not *require a* fatty acid ester. See *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 U.S.P.Q. 2d 1508 (Fed. Cir. 2001); "To

anticipate, the reference must...enable one of skill in the art to make and use the claimed invention." *Kabara* simply does not meet this standard.

Kabara enables only a composition wherein the efficacy of "certain glycerol fatty acid esters can be dramatically increased..." (*Kabara*, p. 3, line 31.) It does not state that fatty acid esters can be added as an option to the other elements of the composition. Even the examiners admitted this critical difference in an April 14, 2006 Action by stating, "At present, we agree with applicant that fatty acid esters are *required in the reference.*" (Action at p. 3, *emphasis added.*) No where in any interpretation of *Kabara* does the examiner contend that a composition that *requires* the presence of a fatty acid ester enables a claim that *does not require* a fatty acid ester. If the rejection based on *Kabara* is maintained, Applicants respectfully request that such an enablement be identified from *Kabara.*

Further, *Kabara* does not disclose or enable a solvent in sufficient concentration to anticipate the claims of this application. The present invention is directed to a lipophilic solvent plus at least two fatty acids that are between C_8 and C_{14}, where the solvent concentration of this invention is between 60% and 95%. *Kabara*, on the other hand, lists solvent concentration as between about 5% and about 60%. The present application states that a "lipophilic polar solvent" or a lipophilic solvent having a dielectric constant of greater than 25 contributes to a greater degree of antimicrobial efficacy, whereas *Kabara* is silent on that topic. Instead, *Kabara* discloses only the use of a "pharmaceutically accepted topical carrier" material that can "codissolve or suspend the materials used in the composition". (*Kabara*, p. 4, lines 49-50 and p. 5, lines 27-28.) This is not a teaching or an enablement of the present invention.

The composition of the solvent or carrier in the present invention is important because the solvent must be lipophilic so that the fatty acid active ingredient can be solublized in the carrier

(it cannot be solublized in water). It should also be relatively polar or at least have a dielectric constant of greater than 25 so the composition can be efficacious in killing microorganisms. The present invention recites a lipophilic solvent in a relatively high concentration whereas the solvent in *Kabara* is simply a "pharmaceutically accepted carrier," in a relatively low concentration (*Kabara*, p.10, line 29.) These terms and functions are not interchangeable.

Further, *Kabara*'s use of a solvent is not central to the purpose of the invention other than to dissolve or suspend the active ingredient(s) whereas the present invention requires that the pharmaceutically-accepted carrier not only be lipophilic, but it must be polar or at least have a dielectric constant greater than 25 to work. *Kabara* never recognizes that the "carrier" in a high concentration can be an active ingredient. If it had, *Kabara* would disclose a higher percentage of the "pharmaceutically accepted carrier" such as 90%, for example. Thus, *Kabara* teaches away from the present invention because it fails to recognize or disclose the function of higher concentrations of a solvent and it teaches that such ingredients should be present in lower concentrations than those claimed in the present invention. One skilled in the art would not have known from *Kabara* to modify the teachings of *Kabara* to arrive at the claimed invention. In summary, the lipophilic polar solvents of the present invention not only carry the active ingredients, they allow the ingredients to be active. Therefore, the claims of the present invention are not anticipated or obvious in view of *Kabara*.

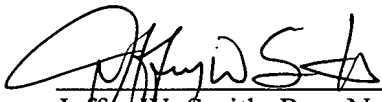
Finally, Applicants note again, as above, that in an April 14, 2006 Action, the examiners described *Kabara* at page 3 by stating, "At present, we agree with applicant that fatty acid esters are required in the reference." This requirement also teaches away from the present invention which does not require fatty acid esters. Instead, the present invention uses a synergistic combination of fatty acids and solvents to obtain the desired effects with no need for fatty acid

esters. *Kabara* cannot simultaneously require the presence of an active ingredient *and* render obvious a claimed composition that does not require that same active ingredient. Thus, the claims would not have been obvious over *Kabara*.

Conclusion

For the foregoing reasons, Applicants respectfully submit that the remaining amended claims are in condition for allowance and that this case be passed to issue.

Respectfully submitted,



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HOW TO USE THIS GUIDE:

The following Dielectric Constants are given at specific temperatures. If your product's temperature is significantly different from those listed there is a good chance that the Dielectric Constant may be different from the values listed.

The products in this reference are listed in alphabetical order and are grouped in sections by the first letter of their name. Proper chemical names were used. If you know the correct spelling of the name of the product you wish to review then use the "FIND" feature on the web browser to locate the name in the list. You may also click on the letter from the alphabetical table to go directly to the beginning of that alphabetic section.

Dielectric Constants Chart

Section A

A B C D E F G H I J K L M N O P Q R S T U V W X Z NUMERIC

ABS RESIN, LUMP 2.4-4.1
ABS RESIN, PELLET 1.5-2.5
ACENAPHTHENE (70° F) 3.0
ACETAL (70° F) 3.6
ACETAL BROMIDE 16.5
ACETAL DOXIME (68° F) 3.4
ACETALDEHYDE (41° F) 21.8
ACETAMIDE (68° F) 41
ACETAMIDE (180° F) 59.0
ACETANILIDE (71° F) 2.9
ACETIC ACID (68° F) 6.2
ACETIC ACID (36° F) 4.1
ACETIC ANHYDRIDE (66° F) 21.0
ACETONE (77° F) 20.7
ACETONE (127° F) 17.7
ACETONE (32° F) 1.0159
ACETONITRILE (70° F) 37.5
ACETOPHENONE (75° F) 17.3
ACETOXIME (24° F) 3
ACETYL ACETONE (68° F) 23.1
ACETYL BROMIDE (68° F) 16.5
ACETYL CHLORIDE (68° F) 15.8
ACETYLE ACETONE (68° F) 25.0
ACETYLENE (32° F) 1.0217
ACETYLMETHYL HEXYL KETONE (66° F) 27.9
ACRYLIC RESIN 2.7 - 4.5
ACTEAL 21.0-3.6
AIR 1
AIR (DRY) (68° F) 1.000536
ALCOHOL, INDUSTRIAL 16-31
ALKYD RESIN 3.5-5
ALLYL ALCOHOL (58° F) 22.0
ALLYL BROMIDE (66° F) 7.0
ALLYL CHLORIDE (68° F) 8.2
ALLYL IODIDE (66° F) 6.1
ALLYL ISOTHIOCYANATE (64° F) 17.2
ALLYL RESIN (CAST) 3.6 - 4.5
ALUMINA 9.3-11.5
ALUMINA 4.5
ALUMINA CHINA 3.1-3.9
ALUMINUM BROMIDE (212° F) 3.4
ALUMINUM FLUORIDE 2.2
ALUMINUM HYDROXIDE 2.2
ALUMINUM OLEATE (68° F) 2.4
ALUMINUM PHOSPHATE 6.0
ALUMINUM POWDER 1.6-1.8
AMBER 2.8-2.9
AMINOALKYD RESIN 3.9-4.2
AMMONIA (-74° F) 25
AMMONIA (-30° F) 22.0
AMMONIA (40° F) 18.9
AMMONIA (69° F) 16.5
AMMONIA (GAS?) (32° F) .0072
AMMONIUM BROMIDE 7.2
AMMONIUM CHLORIDE 7.0
AMYL ACETATE (68° F) 5.0
AMYL ALCOHOL (-180° F) 35.5
AMYL ALCOHOL (68° F) 15.8
AMYL ALCOHOL (140° F) 11.2
AMYL BENZOATE (68° F) 5.1
AMYL BROMIDE (50° F) 6.3
AMYL CHLORIDE (52° F) 6.6
AMYL ETHER (60° F) 3.1
AMYL FORMATE (66° F) 5.7
AMYL IODIDE (62° F) 6.9
AMYL NITRATE (62° F) 9.1
AMYL THIOCYANATE (68° F) 17.4
AMYLAMINE (72° F) 4.6
AMYLENE (70° F) 2.0
AMYLENE BROMIDE (58° F) 5.6
AMYLENETETRARARBOXYLATE (66° F) 4.4
AMYLMERCAPTAN (68° F) 4.7
ANILINE (32° F) 7.8
ANILINE (68° F) 7.3
ANILINE (212° F) 5.5
ANILINE FORMALDEHYDE RESIN 3.5 - 3.6
ANILINE RESIN 3.4-3.8
ANISALDEHYDE (68° F) 15.8
ANISALDOXINE (145° F) 9.2
ANISOLE (68° F) 4.3
ANITMONY TRICHLORIDE 5.3
ANTIMONY PENTACHLORIDE (68° F) 3.2
ANTIMONY TRIBROMIDE (212° F) 20.9
ANTIMONY TRICHLORIDE (166° F) 33.0
ANTIMONY TRICHLORIDE 5.3
ANTIMONY TRICODIDE (347° F) 13.9
APATITE 7.4
ARGON (-376° F) 1.5
ARGON (68° F) 1.000513
ARSENIC TRIBROMIDE (98° F) 9.0
ARSENIC TRICHLORIDE (150° F) 7.0
ARSENIC TRICHLORIDE (70° F) 12.4
ARSENIC TRIIODIDE (302° F) 7.0
ARSINE (-148° F) 2.5
ASBESTOS 3.0 - 4.8
ASH (FLY) 1.7 - 2.0
ASPHALT (75° F) 2.6
ASPHALT, LIQUID 2.5-3.2
AZOXYANISOLE (122° F) 2.3
AZOXYBENZENE (104° F) 5.1
AZOXYPHENITOLE (302° F) 6.8

Section B

A B C D E F G H I J K L M N O P Q R S T U V W X Z NUMERIC

BAKELITE 3.5-5.0
BALLAST 5.4-5.6
BROMACEYTAL BROMIDE 12.6
BROMAL (70° F) 7.6

ISO BUTYL ALCOHOL 18.7-31.7
ISO BUTYL IODIDE 5.8
ISO BUTYL NITRATE 11.9
ISO BUTYLAMINE 4.5
ISO BUTYRIC ACID 2.7
ISO BUTYRONITRILE 20.8
ISO VALERIC ACID (68° F) 2.6
ISO-BUTYL ALCOHOL (-112° F) 31.7
ISO-BUTYL ALCOHOL (32° F) 20 .5
ISO-BUTYL ALCOHOL (68° F) 18.7
ISO-BUTYL IODIDE (68° F) 5.8
ISO-BUTYL NITRATE (66° F) 11.9
ISO-BUTYLACETATE (68° F) 5.6
ISO-BUTYLAMINE (70° F) 4.5
ISO-BUTYRIC ACID (68° F) 2.7
ISO-BUTYRONITRILE 23.9- 20.8
ISO-BUTYRONITRILE (75° F) 20.8
ISO-IODOHEXADECANE 3.5
ISO-PROPYL ALCOHOL (68° F) 18.3
ISO-PROPYL NITRATE (66° F) 11.5
ISO-VALERIC ACID (68° F) 2.7
ISOAMYL VALERATE (19° F) 3.6
ISOAMYL ACETATE (68° F) 5.6
ISOAMYL ALCOHOL (74° F) 15.3
ISOBUTYL FORMATE (66° F) 6.5
ISOBUTYL IODIDE (68° F) 5.8
ISOBUTYL NITRATE (66° F) 11.9
ISOBUTYL RININOLEATE (70° F) 4.7
ISOBUTYL VALERATE (66° F) 3.8
ISOBUTYLAMINE (70° F) 4.5
ISOBUTYLBENZENE (62° F) 2.3
ISOBUTYLBENZOATE (68° F) 5.9
ISOBUTYLENE BROMIDE (68° F) 4.0
ISOBUTYRIC ACID (68° F) 2.6
ISOBUTYRIC ACID (122° F) 2.7
ISOBUTYRIC ANHYDRIDE (68° F) 13.9
ISOBUTYRONITRILE (77° F) 20.8
ISOCAPRONITRILE (68° F) 15.7
ISOOCTANE 2.1-2.3
ISOPHTHALIC ACID 1.4
ISOPRENE (77° F) 2.1
ISOPROPYL ALCOHOL 18.3
ISOPROPYL BENZENE (68° F) 2.4
ISOPROPYL NITRATE 11.5
ISOPROPYLAMINE (68° F) 5.5
ISOPROPYLETHER (77° F) 3.9
ISOQUINOLINE (76° F) 10.7
ISOSAFROL (70° F) 3.4

Section J

A B C D E F G H I J K L M N O P Q R S T U V W X Z NUMERIC

JET FUEL (JP4) (70° F) 1.7
JET FUEL (MILITARY JP4) 1.7

Section K

A B C D E F G H I J K L M N O P Q R S T U V W X Z NUMERIC

KENT WAX 6.5-7.5
KEROSENE (70° F) 1.8
KYNAR 2.0

Section L

A B C D E F G H I J K L M N O P Q R S T U V W X Z NUMERIC

LACTIC ACID (61° F) 22.0
LACTRONITRILE (68° F) 38.4
LAD OXIDE 25.9
LEAD ACETATE 2.5
LEAD CARBONATE (60° F) 18.1
LEAD CHLORIDE 4.2
LEAD NITRATE 37.7
LEAD NOMOXIDE (60° F) 25.9
LEAD OLEATE (64° F) 3.2
LEAD OXIDE 25.9
LEAD SULFATE 14.3
LEAD SULFITE 17.9
LEAD TETRACHLORIDE (68° F) 2.8
LIME 2.2 - 2.5
LIMONENE (68° F) 2.3
LINDE 5A MOLECULAR SIEVE, DRY 1.8
LINOLEIC ACID (32° F) 2.6 - 2.9
LINSEED OIL 3.2-3.5
LIQUIFIED AIR 1.5
LIQUIFIED HYDROGEN 1.2
LITYIUM CHLORIDE 11.1
LONONE (65° F) 10.0
LPG 1.6-1.9

Section M

A B C D E F G H I J K L M N O P Q R S T U V W X Z NUMERIC

m-BROMOANILINE (66° F) 13.0
m-BROMOTOLUENE (137° F) 5.4
m-CHLOROANALINE (66° F) 13.4
m-CHLOROTOLUENE (68° F) 5.6
m-CREOSOL 5
p-CRESOL (24° F) 5.0
o-CRESOL (77° F) 11.5
m-DICHLOROBENZENE (77° F) 5.0
m-DINITRO BENZENE (68° F) 2.8
m-NITROTOLUENE (68° F) 23.8
m-SYLENE 2.4
m-TOLUIDINE (64° F) 6.0
m-XYLENE (68° F) 2.4
MAGANESE DIOXIDE 5-5.2
MAGNESIUM OXIDE 9.7
MAGNESIUM SULFATE 8.2
METHYL ALCOHOL (-112° F) 56.6
METHYL ALCOHOL (32° F) 37.5
METHYL ALCOHOL (68° F) 33.1
METHYL BENZOATE (68° F) 6.6
METHYL BUTANE (68° F) 1.8
METHYL BUTYL KETONE (62° F) 12.4
METHYL BUTYRATE (68° F) 5.6
METHYL CHLORIDE (77° F) 12.9
METHYL CHLOROACETATE (68° F) 12.9
METHYL ETHER (78° F) 5.0
METHYL ETHYL KETONE (72 ° F) 18.4
METHYL ETHYL KETOXIME (68° F) 3.4
METHYL FORMATE (68° F) 8.5
METHYL HEPTANOL (68° F) 5.3
METHYL IODIDE (68° F) 7.1
METHYL KEXYL KETONE (62° F) 10.7